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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
RINES, ROBERT D	

ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 01/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/020,364	CLEMENTI, WILLIAM A.	
	Examiner	Art Unit	
	Robert D. Rines	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/25/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

[1] This communication is in response to the patent application filed 12 December 2001. The IDS statement filed 25 March 2002 has been entered and considered. Claims 1-21 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

[2] Claims 11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yarin et al. (United States Patent #6,294,999) in view of Cummings, Jr. (United States Patent #5,301,105).

[A] As per claim 11, Yarin et al., teaches a computer-readable medium structured to communicate with smart packages for medicines through an electronic medium and containing instructions for determining the compliance of a patient with a medicine regimen (Yarin et al.; col. 5, lines 34-48), by: collecting data from said smart packages (Yarin et al.; col. 7, lines 15-21); and analyzing data to determine the compliance level of the patient (Yarin et al.; col. 11, lines 10-26).

[i] The invention of Yarin et al. is primarily directed to the software and hardware components of a "smart tray" and associated mechanisms for collection of compliance data (Yarin et al.; col. 5, lines 14-20 and lines 34-47). Although it is clear that Yarin et al., intends that the invention be practiced with more than a single patient participant, Yarin et al., fails to specifically teach storing data in a database regarding a plurality of patients and a plurality of medicines. Similarly, although Yarin et al. includes consideration of data that is clearly collected from outside sources (i.e., stakeholders) such as drug side effect and contraindicated drug-drug interactions, Yarin et al., fails to expressly disclose the step of electronically collecting input data from stakeholders.

[ii] However, Cummings teaches storing said data in said database (Cummings Jr.; col. 4, lines 30-39); storing a database which includes information regarding a plurality of patients and a plurality of medicines (Cummings, Jr.; col. 4, lines 30-39, col. 5, lines 9-14, and col. 9, lines 47-52); and collecting input data from said stakeholders through said electronic communication medium (Cummings Jr.; col. 4, lines 53-62, and col. 8, lines 15-21).

[iii] It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Yarin et al., with those of Cummings. Such combination would have resulted in a system and method capable of collecting compliance data from individual patients using a medication "Smart Tray" that is capable of monitoring and reporting to third parties a patient's compliance with various treatment regimens, including medication regimens (Yarin et al.; col. 3, lines 20-25). Further, such a system would serve to

enter and store the colleted compliance data in databases (Cummings, Jr.; col. 4, lines 30-39) such that analysis of the data could serve to enhance periodic monitoring and review of a patient's adherence to health recommendations (Cummings, Jr.; col. 8, lines 22-34). The motivation to combine the teachings would have been to provide enhanced compliance data through a system that facilitates complete integration of the essential elements to provide patients with complete and comprehensive health care (Cummings, Jr.; col. 1, lines 54-60). Further motivation would have been to enhance systems for the analysis of treatment protocols and diagnostic smart systems that serve as aids in treatment planning and diagnostic test selection (Cummings, Jr.; col. 1, lines 65-68 and col. 2, lines 1-2).

[B] As per claim 14, Yarin et al., teaches: a) the step of collecting data from said smart packages is an on-going process and said analysis to determine a compliance level is repeated over time (Yarin et al.; col. 7, lines 15-21, and col. 49-57); and b) said step of analyzing data to determine the compliance level of the patient is repeated over time (Yarin et al.; col. 7, lines 15-21, and col. 49-57).

[i] Regarding claim 14, the obviousness and motivation to combine as discussed with regard to claim 11 above are applicable to claim 14 and are herein incorporated by reference.

[3] Claims 12-13, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yarin et al. and Cummings, Jr., as applied to claim 11 above, and further in view of Aten et al. (United States Patent #4,823,982).

[A] As per claim 12, Yarin et al., teaches that the data collected from said stakeholders includes data regarding the side effects of a medicine and interactions between medicines (Yarin et al.; col. 3, lines 65-67 and col. 4, lines 1-11). Yarin et al., fails to expressly teach inclusing the expected results of a medication or treatment protocol in the collected data.

[i] However, Aten et al., teaches collection of data regarding the expected results of medicines (Aten et al.; col. 15, lines 5-16).

[ii] It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Yarin et al., and Cummings, with those of Aten et al. Such combination would have resulted in a prescription/medication monitoring system that enabled the user to determine whether two or more medicaments are contraindicated (Yarin et al.; col. 4, lines 1-5). Further, such as system would include a measure of the effectiveness of the doses taken (Aten et al.; col. 15, lines 5-16). The motivation to combine the teachings would have been to use gathered patient compliance data to compare the actual dosing intervals to the prescribed dosing intervals to determine how well the actual medication levels matched the prescribed levels (Aten et al.; col. 15, lines 5-15). Further motivation would have been to provide

a thorough evaluation of patient compliance to the prescribed regimen (Aten et al.; col. 15, lines 22-25).

[B] As per claim 13, Cummings, teaches that the data collected from said stakeholders includes data regarding diagnostic medical test results, and data regarding the adherence to exercise and diet regimens by a patient (Cummings Jr.; col. 8, lines 22-34, and col. 10, lines 18-26).

[i] Regarding claim 13, the obviousness and motivation to combine as discussed with regard to claims 11 and 12 above are applicable to claim 13 and are herein incorporated by reference.

[C] As per claim 15, while Cummings teaches allowing stakeholders to access patient data through an electronic medium (Cummings, Jr.; Abstract, col. 1, lines 54-60, and col. 8, lines 15-21), Cummings fails to teach a calculated compliance value or that a calculated compliance value is among the patient data accessible by stakeholders. Although Yarin et al., teaches the further step of analyzing data to determine a compliance-behavior level of the patient (Yarin et al.; col. 5, lines 25-32), Yarin et al., does not teach quantifying a patient's compliance-behavior level as a value or further allowing stakeholders to access a quantified compliance value or rating.

[i] However, Aten et al. teaches analyzing data to determine a compliance-behavior value of the patient (Aten et al.; col. 14, lines 67-68 and col. 15, lines 1-4).

[ii] Regarding claim 15, the obviousness and motivation to combine the teachings of Yarin et al., Cummings, as discussed with regard to claim 11 above are applicable to claim 15 and are herein incorporated by reference.

[ii] Regarding the addition of the teachings of Aten et al. to claim 15, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Yarin et al. and Cummings with those of Aten et al. Such combination would have enabled the compliance level assessment of Yarin et al. (Yarin et al.; col. 5, lines 25-32) to be enhanced by calculating several compliance scores from patient data (Aten et al.; col. 14, lines 67-68). The motivation to combine the teachings would have been help patients take medications per a prescribed schedule and to evaluate the patient's actual compliance to the regimen (Aten et al.; col. 2, lines 54-65). Further motivation would have been to provide an evaluation of patient compliance to the prescribed regimen and the probable effectiveness of the drug therapy (Aten et al.; col. 15, lines 17-25).

[4] Claims 1-4, 8-10, 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yarin et al. in view of Cummings, Jr., and further in view of Snowden et al., (United States Patent Application Publication #2002/0026332).

[A] As per claim 1, Yarin et al., teaches a method of disseminating medical information to increase patient compliance with a medical regimen, said method comprising the steps of: providing medicine to a patient in a smart package (Yarin et al.; Abstract, and col. 3, lines 20-40); providing a device structured to allow said smart packages to interact through an electronic communication medium (Yarin et al.; col. 3, lines 42-51); collecting data from said smart packages (Yarin et al.; col. 7, lines 15-21); and analyzing data to determine the compliance level of the patient (Yarin et al.; col. 11, lines 10-26).

[i] Yarin et al., fails to expressly disclose creating a database with a plurality of medicines and a plurality of patients, a system structured to allow a plurality of stakeholders to electronically access the database and input data, storing patient compliance data in the database, creating patient reports, and making reports accessible to a patient.

[ii] However, Cummings teaches creating a database which includes information regarding a plurality of patients and a plurality of medicines (Cummings, Jr.; col. 4, lines 30-39, col. 5, lines 9-14, and col. 9, lines 47-52); providing a system structured to allow a plurality of stakeholders to access said database and input data into said database through an electronic communication

medium (Cummings, Jr.; Abstract, col. 1, lines 54-60, and col. 8, lines 15-21); collecting input data from said stakeholders in said database through an electronic communication medium (Cummings Jr.; col. 4, lines 53-62, and col. 8, lines 15-21); storing said data in said database (Cummings Jr.; col. 4, lines 30-39); and creating a patient report for each said patient having data relevant to each said patient (Cummings Jr.; col. 8, lines 15-34, col. 9, lines 39-46, and col. 12, lines 34-43). Cummings, fails to teach patient access to patient reports.

[iii] However, Snowden et al., teaches allowing each said patient to access his or her patient report through an electronic communication medium (Snowden et al.; Abstract and paragraphs [0075] [0104]).

[iv] It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Yarin et al., with those of Cummings, Jr., and further with those of Snowden et al. Such combination would have resulted in a system and method capable of collecting compliance data from individual patients using a medication "Smart Tray" that is capable of monitoring and reporting to third parties a patient's compliance with various treatment regimens, including medication regimens (Yarin et al.; col. 3, lines 20-25). Further, such a system would serve to enter and store the colleted compliance data in databases (Cummings, Jr.; col. 4, lines 30-39) such that analysis of the data could serve to enhance periodic monitoring and review of a patient's adherence to health recommendations (Cummings, Jr.; col. 8, lines 22-34). Additionally, such a system would have enabled compliance reports to be stored in a secure repository along with other personal medical records owned and

controlled by the patient such that the patient could access reports and make such reports accessible to appropriate care providers, insurers and suppliers (Snowden et al.; Abstract). The motivation to combine Yarin et al., with Cummings would have been to provide enhanced compliance data through a system that facilitates complete integration of the essential elements to provide patient with complete and comprehensive health care (Cummings, Jr.; col. 1, lines 54-60). Motivation to additionally combine Snowden et al. would have been to allow patients to play a more active role in the management and maintenance of their health (Snowden et al.; paragraph [0102]).

[B] As per claim 2, Yarin et al., teaches wherein said data includes data regarding the side effects of a medicine and interactions between medicines (Yarin et al.; col. 3, lines 65-67 and col. 4, lines 1-11). Cummings teaches data is input by said stakeholders (Cummings Jr.; col. 4, lines 53-62, and col. 8, lines 15-21).

[C] As per claim 3, Cummings teaches wherein said data input by said stakeholders includes data regarding at least one of: the expected results from a medicine, diagnostic medical test results on a patient, data regarding the adherence to exercise, or diet regimens by a patient (Cummings Jr.; col. 8, lines 22-34, and col. 10, lines 18-26,).

[D] As per claim 4, Yarin et al. teaches said step of collecting data from said smart packages is an on-going process and said analysis to determine a compliance level is repeated periodically (Yarin et al.; col. 7, lines 15-21, and col. 49-57). Cummings teaches said step of creating a

patient report is repeated periodically (Cummings Jr.; col. 2, lines 35-42, col. 8, lines 15-34, and col. 9, lines 39-46).

[E] As per claim 8, Cummings teaches wherein said stakeholders are selected from the group including patients, doctors, insurance companies, pharmaceutical companies, pharmaceutical distributors, and healthcare providers (Cummings, Jr.; col. 1, lines 54-60).

[F] As per claim 9, Cummings teaches said insurance company providing said patient with insurance at a rate (Cummings, Jr.; col. 4, lines 53-62); said insurance company adjusting said rate for a patient based on said patient's compliance-behavior value (Cummings. Jr.; col. 8, lines 35-54); and updating said patient report with information about said adjustment in said rate (Cummings, Jr.; col. 9, lines 39-46).

NOTE: Cummings does not employ the terminology of reducing a premium or insurance rate but rather indicates that "health incentives and rewards" may be included. Cummings further indicates that such rewards or "bonuses may be credited to participants according to the extent to which they adhere to their personalized recommended preventative health program or to the extent to which their own personal draw upon health resources fall below specified levels" (Cummings, Jr.; col. 8, lines 47-54). The examiner is interpreting the "rewards and bonuses" of Cummings to be encompassing of the applicant's desire to financially reward the patient for compliance with a medical regimen.

[G] As per claim 10, Cummings teaches a method wherein said stakeholders include patients, doctors, insurance companies, pharmaceutical companies, pharmaceutical distributors, and healthcare providers (Cummings, Jr.; col. 1, lines 54-60).

[i] Regarding claims 2-4 and 8-10, the obviousness and motivation to combine as discussed with regard to claim 1 above are applicable to claims 2-5 and 8-10 and are herein incorporated by reference.

[H] As per claim 16, Yarin et al., teaches a computer-readable medium containing a data structure for storing data relating to the compliance of a patient with a medicine regimen containing data relating to a plurality of medicines (Yarin et al.; col. 5, lines 34-48, col. 5, lines 49-67, and col. 6, lines 1-5). Yarin et al., further teaches data identifying when a smart package that contains the medicine is used (Yarin et al.; col. 8, lines 49-58). Snowden et al., teaches an account for each of a plurality of patients (Snowden et al.; paragraph [0111] [0113]). Cummings teaches data identifying the medicines being taken by each a patient (Cummings, Jr.; col. 9, lines 39-52).

[i] Regarding claim 16, the obviousness and motivation to combine Yarin et al., with Cummings as discussed with regard to claim 11 above are applicable to claim 16 and are herein incorporated by reference.

[ii] Regarding the addition of Snowden et al., it would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Yarin et al., and Cummings with those of Snowden et al. Such combination would have enabled patient data, including prescriptions, to be stored in a secure repository along with other personal medical records owned and controlled by the patient such that the patient could access reports and make such reports accessible to appropriate care providers, insurers and suppliers (Snowden et al.; Abstract). The motivation to combine the teachings would have been to advantageously have an individual's healthcare records stored in a permanent database (Snowden et al.; paragraph [0074]) and to allow patients to play a more active role in the management and maintenance of their health (Snowden et al.; paragraph [0102]).

[I] As per claim 17, Snowden et al., teaches patient accounts (Snowden et al.; paragraph [0104]). Cummings teaches data input by a doctor regarding compliance by a patient (Cummings, Jr.; col. 8, lines 15-21 and lines 35-54).

[i] Regarding claim 17, the obviousness and motivation to combine as discussed with regard to claims 11 and 16 above are applicable to claim 17 and are herein incorporated by reference.

[J] As per claim 18, Yarin et al., teaches a system for disseminating medical information to increase patient compliance with a drug regimen comprising: a smart package for storing medicine (Yarin et al.; Abstract, and col. 3, lines 20-40); a means for said smart packages to interact with stakeholders through an electronic communication medium (Yarin et al.; col. 3,

lines 42-51); a means for collecting data from said smart packages and storing said data (Yarin et al.; col. 7, lines 15-21); and a data analyzing component that analyzes said data from said smart packages to determine the compliance level of the patient (Yarin et al.; col. 11, lines 10-26).

[i] Yarin et al., fails to teach a computer controlled by an administrator, a component database including information regarding a plurality of patients and medicines, storing data in a database, means for a plurality stakeholders to access data and input data into the database, generating patient reports or enabling patient access to generated reports or patient information.

[ii] However, Cummings teaches a component storing a database which includes information regarding a plurality of patients and a plurality of medicines (Cummings, Jr.; col. 4, lines 30-39, col. 5, lines 9-14, and col. 9, lines 47-52); a means for a plurality of stakeholders to access said database and input data into said database through an electronic communication medium (Cummings, Jr.; Abstract, col. 1, lines 54-60, and col. 8, lines 15-21); a means for recording input data from said stakeholders in said database through an electronic communication medium (Cummings Jr.; col. 4, lines 53-62, and col. 8, lines 15-21); and a patient report generating component that creates a patient report for each said patient (Cummings Jr.; col. 8, lines 15-34, col. 9, lines 39-46, and col. 12, lines 34-43), said patient report having data relevant to each said patient (Cummings Jr.; col. 8, lines 15-34, col. 9, lines 39-46, and col. 12, lines 34-43).

[iii] Cummings fails to teach a computer controlled by an administrator and patient access to reports through an electronic medium.

[iv] However, Snowden et al., teaches a computer controlled by an administrator (Snowden et al.; paragraph [0075] [0103); and a means for allowing each said patient to access his or her patient report through an electronic communication medium (Snowden et al.; Abstract and paragraphs [0075] [0104]).

[v] It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Yarin et al., with those of Cummings, Jr., and further with those of Snowden et al. Such combination would have resulted in a system and method capable of collecting compliance data from individual patients using a medication "Smart Tray" that is capable of monitoring and reporting to third parties a patient's compliance with various treatment regimens, including medication regimens (Yarin et al.; col. 3, lines 20-25). Further, such a system would serve to enter and store the colleted compliance data in databases (Cummings, Jr.; col. 4, lines 30-39) such that analysis of the data could serve to enhance periodic monitoring and review of a patient's adherence to health recommendations (Cummings, Jr.; col. 8, lines 22-34). Additionally, such a system would have enabled administrative control over the gathering and integration of clinical, encounter, and compliance data to be stored in a secure repository along with other personal medical records such that the patient could access reports and make such reports accessible to appropriate care providers, insurers and suppliers (Snowden et al.; Abstract and paragraph [0075]). The motivation to combine Yarin et al., with Cummings would have been to provide enhanced compliance data through a system that facilitates complete integration of the essential elements to provide patient

with complete and comprehensive health care (Cummings, Jr.; col. 1, lines 54-60). Motivation to additionally combine Snowden et al. would have been to allow patients to play a more active role in the management and maintenance of their health (Snowden et al.; paragraph [0102]).

[K] As per claim 19, Cummings teaches said component storing a database, said data analyzing component, and said patient report generating component (Cummings Jr.; col. 8, lines 15-34, col. 9, lines 39-46, and col. 12, lines 34-43). Snowden et al., teaches said computer controlled by an administrator (Snowden et al.; paragraph [0075] [0103).

[L] As per claim 20, Yarin et al., teaches a system wherein said means for collecting data from said smart packages is a base station (Yarin et al.; col. 6, lines 45-55).

[M] As per claim 21, Yarin et al., teaches a system wherein said means for allowing each said patient to access his or her patient report is a computer (Snowden et al.; paragraph [0105]).

[i] Regarding claims 19-21, the obviousness and motivation to combine as discussed with regard to claim 18 above are applicable to claims 19-21 and are herein incorporated by reference.

[5] Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yarin et al., Cummings, Jr., and Snowden et al., as applied to claim 1 above, and further in view of Aten et al.

[A] As per claim 5, Snowden et al., does not teach a compliance-behavior value or assessment assigned to a patient. While Cummings teaches allowing stakeholders to access patient data through an electronic medium (Cummings, Jr.; Abstract, col. 1, lines 54-60, and col. 8, lines 15-21), Cummings fails to teach a calculated compliance value or that a calculated compliance value is among the patient data accessible by stakeholders. Although Yarin et al., teaches the further step of analyzing data to determine a compliance-behavior level of the patient (Yarin et al.; col. 5, lines 25-32), Yarin et al., does not teach quantifying a patient's compliance-behavior level as a value or further allowing stakeholders to access a quantified compliance value or rating.

[i] However, Aten et al. teaches analyzing data to determine a compliance-behavior value of the patient (Aten et al.; col. 14, lines 67-68 and col. 15, lines 1-4).

[ii] Regarding claim 5, the obviousness and motivation to combine the teachings of Yarin et al., Cummings, and Snowden et al., as discussed with regard to claim 1 above are applicable to claim 5 and are herein incorporated by reference.

[iii] Regarding the addition of the teachings of Aten et al. it would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Yarin et al., Cummings, and Snowden et al., with those of Aten et al. Such combination would have enabled the compliance level assessment of Yarin et al. (Yarin et al.; col. 5, lines 25-32) to be enhanced by calculating several compliance scores from patient data (Aten et al.; col. 14, lines 67-68). The motivation to combine the teachings would have been help patients take medications per a prescribed schedule and to evaluate the patient's actual compliance to the regimen (Aten et al.; col. 2, lines 54-65). Further motivation would have been to provide an evaluation of patient compliance to the prescribed regimen and the probable effectiveness of the drug therapy (Aten et al.; col. 15, lines 17-25).

[B] As per claim 6, Aten et al., teaches including the steps of (a) formulating a recursive algorithm (Aten et al.; col. 16, lines 12-45); b) comparing the data regarding a patient with a pre-defined set of optimal criteria (Aten et al.; col. 15, lines 21-31); and c) adjusting the patient's compliance-behavior value as the patient's compliance improves or declines (Aten et al.; col. 16, lines 45-67).

[C] As per claim 7, Aten et al., teaches the step of analyzing data to determine a compliance-behavior value includes the step reducing the compliance behavior value to a number or a code (Aten et al.; col. 16, line 43).

[i] Regarding claims 6 and 7, the obviousness and motivation to combine as discussed with regard to claim 5 above are applicable to claims 6 and 7 and are herein incorporated by reference.

Conclusion

[6] The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Portwood et al., SYSTEM AND METHOD FOR IMPROVING COMLIANCE OF A MEDICAL REGIMEN, United States Patent #6,305,377

Zoltan, DEVICE FOR INDICATING LAST MEDICATION USAGE, United States Patent #4,419,016

Edelson et al., PRESCRIPTION CREATION SYSTEM, United States Patent #5,737,539

Lester et al., SYSTEM AND METHOD FOR DRUG MANAGEMENT, United States Patent #6,021,392

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert D. Rines whose telephone number is 571-272-5585. The examiner can normally be reached on 8:30am - 5:00pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RDR

1/10/06

C. LUKE GILLIGAN
PATENT EXAMINER